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the succeeding fiscal year will be established based upon this review. A retroactive adjustment in the amount paid under the interim rate will be made in accordance with \$413.64(f). If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment will be made directly between that contractor and the OPO or laboratory.

(f) For services furnished on or after April 1, 1988, no payment may be made for services furnished by an OPO that does not meet the requirements of part 486, subpart G of this chapter.

(g) Appeals. Any OPO or histocompatibility laboratory that disagrees with a contractor's cost determination under this section is entitled to an contractor hearing, in accordance with the procedures contained in §§ 405.1811 through 405.1833, if the amount in controversy is \$1,000 or more.

[62 FR 43668, Aug. 15, 1997, as amended at 71 FR 31046, May 31, 2006]

§413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in §486.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal contractors. Medicare costs are based on the ratio of the number of usable kidneys transplanted into Medicare ficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes.

OPO must submit a request to the contractor for review and approval of these arrangements.

[62 FR 43668, Aug. 15, 1997, as amended at 71 FR 31046, May 31, 2006]

§413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

- (a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in §486.302 (only covered organs will be paid for on a reasonable cost basis).
- (b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal contractors.
- (c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

§413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

Except as noted in §413.174(f), items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in §413.217 of this part, are paid under the ESRD prospective payment system described in §413.215 through §413.235 of this part.

- (a) Qualifications for payment. To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.
- (b) Payment for items and services. CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and services defined in §413.217 of this part either directly or under arrangements.

[75 FR 49199, Aug. 12, 2010]